

The opinion in support of the decision being entered today was not written for publication and is not precedent of the Board.

Paper No. 37

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte PAUL CALABRESI and JAMES W. DARNOWSKI

Appeal No. 1996-3866
Application 08/087,957

ON BRIEF

Before William F. Smith, Robinson and Mills, Administrative Patent Judges.

MILLS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. §134 from the examiner's final rejection of claims 14, 15 and 17-20, which are all of the claims pending in this application.

We reverse.

Claim 14 is illustrative of the claims on appeal and reads as follows:

14. A method of treating a mammal suffering from carcinoma to inhibit growth of said carcinoma which comprises administering to said mammal effective doses of 3'-azido-3'-deoxythymidine and methotrexate, wherein said 3'-azido-3'-deoxythymidine and said methotrexate are administered within a 48 hour time period, and are more effective than the combined effects of separate administration of 3'-azido-3'-deoxythymidine and methotrexate.

The prior art reference relied upon by the examiner is:

Minor, Proceedings of ASCO, Vol. 7, No. 4, Abstract No. 16, 1988.

Ground of Rejection

Claims 14-15 and 17-20 stand rejected under 35 U.S.C. § 103 as obvious over Minor.

DISCUSSION

In reaching our decision in this appeal, we have given consideration to the appellants' specification and claims, to the applied prior art reference, and to the respective positions articulated by the appellants and the examiner.

Rather than reiterate the conflicting viewpoints advanced by the examiner and the appellants regarding the noted rejection, we make reference to the examiner's Answer for the examiner's reasoning in support of the rejection, and to the appellants' Brief and Reply Brief for the appellants' arguments thereagainst. As a consequence of our review, we make the determinations which follow.

35 U.S.C. § 103

Claims 14-15 and 17-20 stand rejected under 35 U.S.C. § 103 as obvious over Minor.

In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a prima facie case of obviousness. See In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). A prima facie case of obviousness is established when the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art. In re Bell, 991 F.2d 781, 783, 26 USPQ2d 1529, 1531 (Fed. Cir. 1993). An obviousness analysis requires that the prior art both suggest the claimed subject matter and reveal a reasonable expectation of success to one reasonably skilled in the art. In re Vaeck, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991).

According to the examiner, Minor teaches “the combination of AZT (zidovudine) and methotrexate for treating cancer (Kaposi's Sarcoma) in patients.” Answer, page 3. The examiner also finds that “the reference clearly shows that while four patients were on zidovudine (AZT) they received chemotherapy, methotrexate. In view of this, one of ordinary skill in the art would be motivated to administer AZT with methotrexate to treat cancer. The specific cancers being treated are clearly within the skill of the art.” Id.

The manner in which the examiner has put forth the statement of rejection has made it difficult for us to clearly determine what the examiner considers to be obvious. For example, in reading the statement rejection, the examiner has indicated that “one skilled in the art would be motivated to administer AZT with methotrexate to treat cancer.” Answer, page 3. The examiner has never explained why, in view of such motivation, one skilled in the art would consider the claimed subject matter as a whole to have been obvious.

As set forth in the Manual of Patent Examining Procedure (MPEP) § 706.02(j) (6th ed., no. 3, July 1997),

the examiner should set forth . . . (1) the relevant teachings of the prior art relied upon, preferably with reference to the relevant column or page number(s) and line number(s) where appropriate, (2) the difference or differences in the claim over the applied reference(s), (3) the proposed modification of the applied reference(s) necessary to arrive at the claimed subject matter, and (4) an explanation why such proposed modification would have been obvious to one of ordinary skill in the art at the time the invention was made.

Adherence to this model would result in a more coherent, understandable statement of the rejection.

In any event, the claimed method requires that the 3'-azido-3'-deoxythymidine and methotrexate be administered within a 48 hour time period. The examiner has not provided evidence of, and we do not find, any disclosure in Minor which would suggest administration of 3'-azido-3'-deoxythymidine and methotrexate within a 48 hour time period.

Minor describes administration of methotrexate as part of a chemotherapy regimen for treatment of kaposi's sarcoma in AIDS patients on day 22 and sometime "after chemotherapy was stopped" four patients "were begun on zidovudine". Minor, abstract. The abstract is ambiguous as to when AZT treatment was begun. It is mere speculation on the part of the examiner that the AZT treatment of chemotherapy patients commenced on day 24, one day after the chemotherapy regimen stopped on day 23, and at least two days after treatment with methotrexate on day 22.

Conclusions of obviousness must be based upon facts not generalities. See In re Warner, 379 F.2d 1011, 1017, 154 USPQ 173, 178 (CCPA 1967), cert. denied, 389 U.S. 1057 (1968); In re Freed, 425 F.2d 785, 165 USPQ 570, 571 (CCPA 1970). In the present case the examiner has provided no conclusive fact or evidence that the

administration of 3'-azido-3'-deoxythymidine and methotrexate described in Minor was within a 48 hour time period to satisfy the claim.

We note that the record reflects that appellants have filed two Declarations for consideration of the examiner in the application. We find it unnecessary to reach the rebuttal evidence of appellant as we find the examiner has not met the burden of setting forth a prima facie case of unpatentability based on obviousness. In re Oetiker, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992), In re Geiger, 815 F.2d 686, 688, 2 USPQ2d 1276, 1278 (Fed. Cir. 1987).

CONCLUSION

The rejection of claims 14-15 and 17-20 under 35 U.S.C. § 103 as obvious in view of Minor is reversed.

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No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

REVERSED

William F. Smith)	
Administrative Patent Judge)	
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)	BOARD OF PATENT
Douglas W. Robinson)	
Administrative Patent Judge)	APPEALS AND
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